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*D. Lawrence*  
#43  
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PATENT  
Customer No. 22,852  
Attorney Docket No. 2481.1726-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: )  
)  
Petra LOOS et al. ) Group Art Unit: 1743  
)  
Application No.: 09/763,733 ) Examiner: S. Siefke  
)  
Filed: February 27, 2001 )  
)  
For: MINI-BASKET FOR ANALYZING )  
ACTIVE SUBSTANCE RELEASE )  
FROM A MEDICAMENT FORM )

Commissioner for Patents  
Washington, DC 20231

Sir:

**APPEAL BRIEF UNDER 37 C.F.R. § 1.192**

Appellant's Appeal Brief in connection with the above-captioned patent application is hereby submitted in triplicate. A Notice of Appeal was timely filed on September 25, 2002, in response to the final Office Action of June 3, 2002. Each item required by 37 C.F.R. § 1.192 is set forth below.

Pursuant to 37 C.F.R. § 1.192(a), the fee payment of \$300.00 is enclosed with this Appeal Brief.

**I. Real Party In Interest**

The real party in interest is Aventis Pharma Deutschland GmbH, located at Brüningstrasse 50, D-65929 Frankfurt am Main, Germany.

**II. Related Appeals and Interferences**

On information and belief, there are no related Appeals or Interferences.

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### **III. Status Of Claims**

Claims 1-7 have been canceled. Claims 8-31 are currently pending in this application. Claims 25-31 have been withdrawn from consideration as drawn to a non-elected invention. Claims 8-24 are the subject of this appeal. A clean copy of claims 8-24 is found in the Appendix.

### **IV. Status Of Amendments**

No Amendments After Final have been filed in this application.

### **V. Summary Of Invention**

The present invention, as defined by independent claim 8, is directed to a device configured to fit within an in vitro substance release testing apparatus. The device is a mini-basket that includes a mesh basket configured to receive a material to be tested, and a lid including a handle on one side of the lid. The handle is used to move the mini-basket between testing apparatus having different testing mediums, or between different types of testing apparatus, for example, from a rotating basket apparatus to a continuous flow cell apparatus. The basket is not physically connected to the testing apparatus, and therefore can easily be moved between apparatuses by the handle on the lid.

### **VI. Issues**

There is one issue on appeal, as set forth below:

Whether claims 8-24 recite patentable subject matter under 35 U.S.C. § 102(b) based on Mehta et al., U.S. Patent No. 4,856,909.

### **VII. Grouping Of Claims**

Claims 8-24 stand or fall together.

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## VIII. Argument

The final rejection should be reversed for the reasons set forth herein.

Claims 8-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mehta et al., U.S. Patent No. 4,856,909. Page 2 of the Final Rejection.

### Law on Anticipation Under 35 U.S.C. § 102(b):

35 U.S.C. § 102(b) states:

A person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the date of application for patent in the United States.

Accordingly, a person is not entitled to a patent if the claimed invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than a year prior to the filing date of the U.S. patent application. Claims of a patent application not entitled to a patent under the conditions of 35 U.S.C. § 102(b) are rejected by a Patent Examiner as anticipated by the cited prior art patent or printed publication. A claim is anticipated, however, only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053, (Fed. Cir. 1987). Further, an anticipating prior art patent or printed publication must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 1566, 1567, 7 USPQ2d 1315, 1317 (Fed. Cir. 1988).

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The rejection of claims 8-24 under 35 U.S.C. § 102(b) should be withdrawn because Mehta et al. does not disclose, either expressly or inherently, each and every element set forth in the claims. For example, claim 8 requires that at least the following feature of the claimed device be present:

a lid including a handle on one side of the lid.

In rejecting claims 8-24, the Examiner asserted that Mehta et al. discloses the invention as claimed. More specifically, the Examiner asserted that Mehta et al. discloses an apparatus comprising "a cylindrical mesh basket with a handle and a lid made of mesh; a lid with three fixing clips; a metal band around the open end of the basket; [the] basket to be used with a paddle agitator, continuous flow cell, and rotating basket apparatus." Final Rejection, page 3.

In response to Applicants' arguments that Mehta et al. does not disclose a handle, the Examiner asserted that the drive shaft 16 of Mehta et al. may be grasped by a hand and therefore may be considered a handle. The Examiner relied upon a definition of a handle found in Webster's Dictionary, which allegedly states that a handle is "a part that is designed especially to be grasped by the hand" (emphasis added). The Examiner asserted that the cylindrical shape of the drive shaft enables it to be grasped by a hand, and therefore the drive shaft is structurally capable of performing the function of a handle. Final Rejection, page 2.

Applicants disagree with the Examiner's assertion. Mehta et al. does not disclose or suggest the use of a structure especially designed to be grasped by the hand to allow the user to carry the basket or remove the cover of the basket. The drive shaft 16 disclosed in Mehta et al. is not a handle. Contrary to the Examiner's assertion,

the drive shaft is not "designed especially" to be grasped by the hand. Rather, it is designed to interact with inner drive shaft 14 to cause rotation of the basket 18. Further, as shown in Fig. 6, drive shaft 16 appears to be contained within a structure extending from outer drive shaft 12, such that drive shaft 16 is not exposed and therefore, cannot be grasped by a hand. In addition, as shown in Figs. 1 and 2 of Mehta et al., the drive shaft 16, in addition to being inaccessible, is positioned below the testing medium or solvent 20 of the testing apparatus. Appellants assert that shaft 16 cannot function as a handle because it would require a person to insert their hand into the solvent 20, often an acid, in order to grasp the shaft 16 to remove the basket from the solvent. Clearly such positioning of the drive shaft 16 in the solvent 20 contradicts any assertion that drive shaft 16 is "especially designed" for grasping by the hand.

Even assuming arguendo that the drive shaft 16 was accessible to be grasped by the hand, to do so could likely impair the proper operation of the drive shaft. For example, oils and other dirt from the hand could impede proper rotation of the drive shaft. Further, using the drive shaft 16 as a handle could cause stresses on shaft 16 itself and on other parts of the basket 18 and chuck 40 that those parts are not designed to withstand, thus potentially causing permanent damage to the device and/or a person attempting to grasp the drive shaft 16.

During a telephone interview held between Examiner Siefke and Applicants' undersigned representative on September 24, 2002, the Examiner for the first time argued that the "handle" of Mehta et al. is drive shaft 12, an assertion in contradiction to the statements in the Final Office Action. Appellants object to this new grounds of rejection. In addition, Appellants note that there is no physical contact between the

outer drive shaft 12 and the lid of Mehta et al.'s basket, and therefore, outer drive shaft 12 is not on the lid as required by claim 8.

Independent claim 8 of the present application recites a combination including "a mesh basket configured to receive a material to be tested, and a lid including a handle on one side of the lid." The present invention is intended to be used in various types of testing apparatuses, and to be moved between apparatuses containing different solvents. The handle on the lid of the basket facilitates removal of the basket from one apparatus and insertion into a different apparatus.

A handle is defined on page 616 of The American Heritage College Dictionary, (3<sup>rd</sup> ed., 1993), as "[a] part that is designed to be held or operated with the hand." As stated previously and shown in Figs. 2 and 4 of Mehta et al., does not disclose or suggest a part that is designed to be held or operated with the hand. Instead, Mehta et al. discloses a chuck 40 used to close the container and including three spring clips extending around the lid to engage with slots 32 of end ring 26. Chuck 40 is formed around and connected to horizontal drive shaft 16 via bearing 62 and bevel gear 52. Horizontal drive shaft 16 is in turn connected to inner drive shaft 14 and outer drive shaft 12 via bevel gear 50 and a couple of bearings. Mehta et al. is completely silent as to the use of a handle on the lid of its apparatus, and the figures do not disclose or suggest the use of a handle.

Further, there is no motivation for one of ordinary skill in the art to provide Mehta et al. with a handle on its lid. A handle would interfere with the operation of the horizontal drive shaft 16, thus rendering Mehta et al.'s apparatus inoperable. Further, a handle on the lid of the basket of Mehta et al. would be inoperable because it could not

be reached without a user placing his hand into the testing medium (solvent). Thus, Mehta et al. cannot anticipate or render obvious the invention recited in claim 8.

Finally, the Examiner is incorrect in his assertion that the basket of Mehta et al. may be used with a paddle agitator, continuous flow cell, and rotating basket apparatus. Final Rejection, page 3. Mehta et al. discloses a rotating basket apparatus. Chuck 40 closes the container and includes three spring clips 30 extending around the chuck 40 to engage with slots 32 of end ring 26. Chuck 40 is formed around and connected to horizontal drive shaft 16 via bearing 62 and bevel gear 52. Horizontal drive shaft 16 is in turn connected to inner drive shaft 14 and outer drive shaft 12 via bevel gear 50 and a couple of bearings 60. Drive shaft 12 is connected to a drive system 63. The basket 18 and chuck 40 of Mehta et al. are an integral portion of the testing apparatus of Mehta et al. Unlike the present invention, the basket 18 and chuck 40 of Mehta et al. are not configured or intended to be used with different types of testing apparatus. Mehta et al. does not disclose or suggest use of its device with a paddle agitator or a continuous flow cell. Thus, Mehta et al. cannot anticipate or render obvious claims 13, 14, and 16.

Favorable consideration of claims 8-24 and reversal of this rejection is respectfully requested.

### **Conclusion**

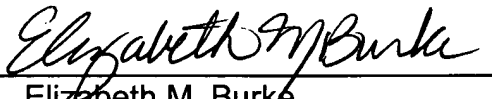
In conclusion, Appellant submits that the rejections of claims 8-24 should be reversed. Mehta et al. does not disclose or suggest the use of a handle on a lid of its basket. Further, there is no motivation to provide a handle for the rotating basket of Mehta et al. because such a handle would be inoperable. Therefore, Mehta et al. cannot anticipate or render obvious claim 8 or any claim that depends therefrom.

To the extent any further extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: March 11, 2003

By:   
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### Appendix of the Claims Appealed

8. A device configured to fit within an in vitro substance release testing apparatus, the device comprising:
- a mesh basket configured to receive a material to be tested; and
  - a lid including a handle on one side of the lid.
9. The device of claim 8, wherein the lid includes at least one fixing clip on a side of the lid opposite the handle.
10. The device of claim 8, wherein the basket is cylindrical in shape and includes an open end and a closed end.
11. The device of claim 10, wherein the basket includes a narrow metal band around at least an open end of the basket.
- ✓ 12. The device of claim 8, wherein the handle includes a bracket configured to allow removal of the device from the testing apparatus.
13. The device of claim 8, wherein the device is configured to fit within a paddle agitator.
14. The device of claim 8, wherein the device is configured to fit within a continuous flow cell.
15. The device of claim 8, wherein the device is configured to fit within a rotating basket apparatus.
16. The device of claim 8, wherein the device is configured to fit within a paddle agitator and a continuous flow cell.
17. The device of claim 8, wherein the material to be tested is a medicament in solid form.
18. The device of claim 8, wherein the lid is formed of a mesh material.

19. The device of claim 8, wherein the lid is a plate.
20. The device of claim 18, wherein the handle is attached to the lid in a manner which maximizes the amount of the lid surface through which a fluid may pass.
21. The device of claim 9, wherein the fixing clip is configured to connect the lid to the basket.
22. The device of claim 9, wherein the lid includes three fixing clips.
23. The device of claim 19, wherein the handle includes a rod.
24. The device of claim 8, wherein the mesh forming the basket is a wire screen fabric.